3

Use of a test as claim in [any of the preceding] claim[s] 1 1 2 further comprising the step of eliminating participants having the genetic basis of Gilbert's Syndrome from a drugs trial. Use of a test as claimed in [any of] claim[s] 1 l[to 3] 5. wherein the method comprises the further step of selecting only participants having genetic basis for Gilbert's Syndrome for a drugs trial. 6. Use of a test claimed in [any of] claim[s]s 1 [to 3] further comprising the step of interpreting the results of the drugs trial in the knowledge that certain participants have Gilbert's Syndrome. Use of a test as claimed in [any of the preceding] claim[s] 1 7. wherein the method comprises the steps of: a) isolating DNA from each sample, 3 b) amplifying the DNA inner region indicating the genetic basis 4 for Gilbert's Syndrome, 5 c) isolating amplified DNA fragments, and 6 d) identifying individuals having the genetic basis of Gilbert's 7 Syndrome. 8 8. Use of a test as claimed in [any of the preceding] claim[s] 1 1 wherein the DNA is amplified using the polymerase chain reaction (PCR) using 2 a radioactively labeled pair of nucleotide primers. 3 Use of a test as claimed in [any of] claim[s] 7 [to 9] wherein 1 the DNA region indicating the genetic basis of Gilbert's Syndrome is the gene 2 encoding UDP-glucuronosyltransferase (UGT). 3 Use of a test as claimed in [any of] claim[s] 7 [to 10] 1 wherein the DNA to be amplified is in an upstream promoter region of the UGT 2 1\*1 exon 1. 3 Use of a test as claimed in [any of] claim[s] 7 [to 11] ÌQ. 1 2 wherein the DNA to be amplified includes the regions between -35 and -55

nucleotides at the 5' end of UGT 1\*1 exon.

Primers for use of a test as claimed in [any of the preceding] claim[s] 1 including primer pairs, AB or CD as follows:

A/B(1,5' -AAGTGAACTCCCTGCTACCTT-3', B,5' -CCACTGGGATCAACAGTATCT-3') or C/D (C,5'-GTCACGTGACACAGTCAAAC-3'; D 5' -TTTGCTCCTGCCAGAGGTT-3').

Respectfully Submitted,

Allan Ratner, Reg. No. 19,717 Attorney for Applicant

AR:sls

Dated: September 1, 1998

Suite 301 One Westlakes, Berwyn P.O. Box 980 Valley Forge, PA 19482-0980 (610) 407-0700

The Assistant Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

EXPRESS MAIL Mailing Label Number: EL 013 897 799 US Date of Deposit: September 1, 1998

I hereby certify that this paper and fee are being deposited, under 37 C.F.R. § 1.10 and with sufficient postage, using the "Express Mail Post Office to Addressee" service of the United States Postal Service on the date indicated above and that the deposit is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231, Attn: Box PCT (RO/US)

Jan Landis